K022873

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MAR 21 2003

~~510(k) STATEMENT OF SAFETY AND EFFECTIVENESS~~

510k SUMMARY OF SAFETY AND EFFECTIVENESS
RADIATION ATTENUATING SURGICAL GLOVE

Manufacturer:	International Biomedical, Inc. 8508 Cross Park Drive Austin, TX 78754 U.S.A.
Regulatory Affairs Contact:	Amy Pieper 8508 Cross Park Dr. Austin, TX 78754
Telephone:	(512) 873-0033
Date Summary Prepare:	August 27, 2002
Common Name:	Powder-Free Radiation Attenuating Surgical Glove
Classification:	Sugeon's Glove, 79KGO
Predicate Devices:	Radiation Attenuating Surgical Glove by International Biomedical, Inc. (82k1720) and the ESP Radiation Recustion Examination Gloves by Boston Scientific (k891968) and BarrierPlus Synthetic Powder-Free Surgical Gloves y BarrierMed Glove Company (k990710).
Description:	The Powder-Free Radiation Attenuating Surgical Gloves are formulated using neoprene, synthetic latex. The gloves are supplied powder-free and sterile.
Intended Use:	A powder-free surgeon's glove is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious materials and other contaminants. Additionally, the radiation attenuating surgical glove is intended to

be used during medical procedures where hands are necessarily exposed to radiation in order to offer some degree of protection to the hand from radiation. This includes surgical procedures that require the use of fluoroscopy or radiography.

Substantial Equivalence:

Powder Free Radiation Attenuating Surgical gloves are substantially equivalent to the Radiation Attenuating Surgical Gloves in that they have the same intended use, they are both made of synthetic latex, and they are both manufactured in the same way. The Powder Free Radiation Attenuating Surgical gloves are substantially equivalent to the ESP Radiation Recustion Examination Gloves by Boston Scientific in that they have the same intended use and polymers.
The Powder Free Radiation Attenuating Surgical gloves are substantially equivalent to the BarrierPlus Synthetic Powder-Free Surgical Gloves in intended use, design and product features, and physical characteristics.

Summary of Test Results:

Test	Result
Primary Skin Irritation	Glove does not display irritation potential.
Dermal Sensitization	Glove does not display sensitization potential.
Elongation and Tensile Strength	Glove meets or exceeds requirements for synthetic surgical gloves per ASTM D 3577-01a.
Barrier Defects	Glove meets or exceeds requirements per ASTM D3577-01a.
Powder Level	Glove meets powder level requirements for "Powder Free" designation per ASTM D 6124-01.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

Ms. Amy Pieper
Regulatory Affairs
International Biomedical, Incorporated
8508 Cross Park Drive
Austin, Texas 78754

Re: K022873
Trade/Device Name: Radiation Attenuating Neoprene Surgical Gloves, Powder Free (Black)
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: November 25, 2002
Received: January 21, 2003

Dear Ms. Pieper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant's Name:
International Biomedical, Inc.

510(k) Number: K022873

Device Name: Neoprene
Radiation Attenuating Surgical Gloves, Power Free (BLACK)

Indications for Use:

A powder-free surgeon's glove is a device made of synthetic latex that may bear a trace amount of glove powder and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. The radiation attenuating surgical glove is intended to be used during medical procedures where hands are necessarily exposed to radiation in order to offer some degree of protection to the hand from radiation. This includes surgical procedures that require the use of fluoroscopy or radiography.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022873